DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

JUN 19 2001

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Steven Daffer
President
Symedex Medical Aesthetic Solutions
9220 James Avenue South
Minneapolis, Minnesota 55431

Re: MD2000 and MD2 Therapeutic Massagers

Dear Mr. Daffer:

The Promotion and Advertising Policy Staff (PAPS), Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed the June 5 response from Mr. Ronald E. Berglund, Symedex Medical Aesthetic Solutions (Symedex) General Counsel, to our letter dated May 1. Our letter was in regard to the MD2000 and MD2 Therapeutic Massagers. We find Mr. Berglund's response on your behalf unacceptable.

The MD2000 Therapeutic Massager and the MD2 Therapeutic Massager are classified by regulation under Title 21, Code of Federal Regulations, Part 890.5660 [21 CFR 890.5660] as therapeutic massagers and are also devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Claims for therapeutic massagers are currently limited by the agency to the following: (1) temporarily relieves minor muscle aches and pains caused by fatigue or overexertion; (2) temporarily increases local blood circulation; (3) relaxes muscles locally; (4) relieves DOMS (delayed onset muscle soreness); (5) relieves minor muscle aches and pains, relieves muscle spasms, and temporarily improves local blood circulation during burn rehabilitation; (6) temporarily reduces the appearance of cellulite and circumferential body measurements of cellulite treated areas.

The modifications recently made to your web site at the internet address: http://www.symedex.com remain unacceptable because statements appearing on your site continue to claim and/or imply that your therapeutic massagers (MD2000 and MD2) play a role in the treatment of liposuction, that use of these devices can affect interstitial edema, fat hypertrophy, and lipolymphedema, and/or that they can be utilized in medical settings including pre-surgery, intra-operative surgery, and in post-surgical applications. Additionally, your web site names the treatment heads for the MD2 as "lipoapplicator heads" and identifies some of the MD2 inclusion accessories as "Smooth Lipoapplicator (MD229)," "Mini Prong Lipoapplicator (MD225)," and "Liposculpt Therapeutic Cream." These claims imply that the MD2000 and/or MD2 may be used in the treatment of liposuction, reduction of edema, or for pre, intra, and post surgical conditions. None of these claims has been cleared by the agency.

Other representative examples of unacceptable claims appearing on your revised web site include the following:

-"MD2000 Vibratory Percussor Applications"...Your MD2000 and MD2 devices are therapeutic massagers and should be identified as such. Although these devices may function by suctioning or rolling the skin, they are not "vibratory percussors."

-"Many surgeons recommend using the MD2000 immediately before liposuction"

-"During tumescent liposuction, the ultrasonically created fat emulsion is easily absorbed into the third space compartments and therefore is very important to remove. The ability to suction or remove as much of the emulsion from the tissues as possible is critical..."

-"Treating patients following liposculpture may be the most effective application of the MD2000 System."

-MD2 is specially designed with removable and interchangeable lipoapplicator heads"

-"Ideal candidates for liposuction procedures have good skin elasticity and localized areas of excess fat accumulation that have been proven to be resistant to diet and exercise for several years"

Additionally, your page titled, Cellulite Reduction, mentions the physical and physiologic changes that occur in capillaries and superficial fatty tissues such as interstitial edema, fat hypertrophy, and lipolymphedema. By discussing these physiologic changes in conjunction with the MD2000 System, Symedex implies that your therapeutic massager can treat these conditions, which it has not been cleared for.

Your web site also includes testimonial statements from several physicians and includes study results that suggest the MD2 and MD2000 may be used as an adjunct in the treatment of liposuction. Representative statements include, but are not limited, to the following:

-"In recent years, several types of massage devices have been advocated for the treatment of cellulite and to improve the results of liposuction. One such device...is the Symedex MD2000"

-"To evaluate the effectiveness of this device in improving liposuction results, the author used a protocol based on subjective opinions of patients and technicians"

-"The machines have also been recommended as an adjunct to liposuction to improve post-liposuction contour irregularities and to speed recovery."

-"The vibratory action and stroking motion used by the technician may enhance...lymphatic drainage. This may diminish post-trauma inflammatory interactions in the tissue.

From an article by Paul Rose, M.D., (consultant for Symedex) titled, A Preliminary Study of the Effect of Percussive Massage in Post Liposuction Patient Recovery

-"Our current protocol involves pretreatment of the areas to be liposculpted with several sessions of vibratory percussion using the cellulite protocol described by the manufacturer [Symedex], in the hope of breaking down some of the subcutaneous, fibro-fatty/fascial cards"

-..."The MD2000 is used to massage the area for 5 to 15 minutes. The heads recommended for lymphatic drainage ...are used with the "macro" treatment heads at speeds of 30 to 45 oscillations per second"

-...It was quickly found that liposuction was more rapid, required less time and effort, and yielded a smoother contour by the end of the case on the pre-treated sides"

-"There appears to be an improvement in cellulite scores in some patients after liposuction using the MD2000 protocol"

From a testimonial by Edward M. Zimmerman, M.D. reporting his initial experience with the MD2000 and MD2 as an adjunct to tumescent liposuction

-"We have also begun to use the MD2000 immediately post-operatively to remove fluid, decrease drainage, and hopefully speed recovery:

-"...The fat is easier to remove"

From Paul Rose, M.D., in a March 9, 1999 letter to Ron Berglund, Symedex General Counsel

"I routinely start my patients post-liposuction on the package of treatments utilizing the MD2000 System at four weeks post-surgery"

-..."Tremendous benefit in decreasing the post-operative edema as well as evening any slight symmetries subsequent to the liposculpting"

"The MD2000 System treats cellulite effectively by...increasing lymphatic drainage as well as playing some role in the stretching of the connective fibers"

-"...We find a large number of our anti-aging patients requesting the therapy of the MD2000 System"

-I would have no hesitation or reservation in giving the MD2000 Liposculpt Mobilization System the highest possible recommendation"

From Gregory W. Chernoff, M.D., in a December 29, 1999 letter to Steve Trinter, Symedex National Sales Manager

"The MD2000 System is exciting [sic] new technological innovation and a welcome addition to the armamentarium, of those treating liposuction patients."

-"As a surgeon, I find great promise with this system and its potential as useful intra-operative

and post-operative adjuvant to traditional and ultrasonic liposuction"

-Qualitatively, the MD2000 System seem to be as effective if not superior to external ultrasound in the ability to break down fat cells before subjecting them to liposuction"

From Mark L. Zukowski, M.D., in a March 8, 1999 letter to Ron Berglund, Symedex General Counsel

In our letter of January 18, you were previously advised that certain claims which appeared in your advertisements and on your web site went far beyond those recognized by the agency for therapeutic massagers and removed your MD2000 and MD2 devices from exempted status. The claims for which you were previously cited included:

From an advertisement:

- Post-operative swelling
- Less rippling and dimpling of the tissue
- Enhanced circulation of lymph flow for faster recovery
- Immediate and periodic post-operative tissue contouring
- Pre and post surgical tissue stimulation
- Technology for pre-surgery, intra-operative and post-surgical lipoplasty procedures
- Increased lymphatic circulation – massage...can increase the flow of lymph
- Stretching of the vertical connective fibers – suction and cupping gently stretch the septae to repair dimpling and restore a smooth skin surface
- Perpendicular action helps stimulate the flow of ...lymph and loosen and liquefy fluids
- Parallel action helps dislodge, mobilize and direct fluids in select directions
- The MD2000 system treats cellulite effectively and very efficiently by...increasing lymphatic drainage as well as playing some role in stretching of the connective fibers
- Liposculpture doesn't end with the surgery

From the Internet:

- Used before, during, and after liposuction procedures
- Pre-treating patients for 2-3 weeks before surgery may help achieve better lipoplasty results
- It has been theorized that the effect of pre-surgery tissue stimulation and mobilization vibratory percussion helps to break up and liquefy fat for results similar to ultrasound
- The ability to...massage as much of the emulsion from the tissues as possible is critical...contour applicators to assist in...stimulation of soft tissue fluids
- Treating patients experiencing lumpiness or other irregularities following liposculpture may be the most effective application of MD2000....post-surgery tissue stimulation and mobilization...helps to relieve pain, improve patient recovery time, and enhance results
- ...Patients who are not satisfied with the results of their surgeries can be treated with the MD2000 and thereby avoid the need for secondary surgical procedures
- Reduces edema...Helps prevent desiccation and intertriginous changes of the skin
- Helps prevent capsular contracture following breast surgery

- Intra-operative use...is critical to drainage of fluids created...and even distribution of tumescent fluid

As is evident from the above claims, Symedex continues to include some of these identical claims on its current web site despite prior notice that those claims were inappropriate. FDA regulations at 21 CFR 801.4 refer to the objective intent of the persons legally responsible for the labeling of the device.

Promotion of the MD2000 and MD2 therapeutic massagers for the claims on your current web site causes these devices to be misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modifications in the intended use(s) of the devices was not provided to FDA as required by section 510(k) of the Act and the devices were not found to be substantially equivalent to a predicate device.

The MD2000 and MD2 therapeutic massagers are also adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a), or approved applications for investigational device exemptions (IDE's) under section 520(g).

We also note that your web site discusses the use of a "Fotostation Photo Image Measurement System." The system is described as documenting before, during, and after progress following use of the MD2. We believe these references allude to weight loss or loss of inches and we caution Symedex that any such claims for your MD2 and MD2000 have not been cleared by the agency.

Finally, we see that Symedex has scheduled several training sessions from the present through the end of the year (2001) regarding the use of the MD2 and the MD2000 Systems. We caution Symedex that these devices may only be demonstrated, and potential customers trained, for the claims granted by the agency and identified in paragraph 3 of this letter.

This letter is not intended to be an all-inclusive list of deficiencies associated with your MD2000 and MD2 Therapeutic Massagers. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Minneapolis District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Minneapolis District Office (HFR-CE340), 240 Hennepin Avenue, Minneapolis, Minnesota 55401-1912.

Sincerely yours,

for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health